UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS TYLER DIVISION

MERCK & CIE, SOUTH ALABAMA MEDICAL SCIENCE FOUNDATION and PAMLAB L.L.C.

6:12cv27

Plaintiffs,

JURY DEMAND

COMPLAINT

-VS.-

MACOVEN PHARMACEUTICALS, GNOSIS S.P.A. GNOSIS USA INC. and GNOSIS BIORESEARCH S.A.,

Defendants.

Plaintiffs Merck & Cie ("Merck"), South Alabama Medical Science Foundation ("SAMSF") and Pamlab L.L.C ("Pamlab") (collectively, "Plaintiffs") file this Complaint against Defendants Macoven Pharmaceuticals ("Macoven"), Gnosis, S.p.A., Gnosis USA Inc. and Gnosis Bioresearch SA¹ (collectively, "Defendants") and, in support thereof, allege as follows:

NATURE AND BASIS OF ACTION

1. This is a civil action for the infringement of United States Patent Nos. 5,997,915 (the "'915 patent"), 6,011,040 (the "'040 patent"), 6,254,904 (the "'904 patent"), 6,673,381 (the "'381 patent"), 7,674,490 (the "'490 patent"), and 7,172,778 (the "'778 patent"). This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq*.

PARTIES

2. Plaintiff Merck & Cie is a Swiss corporation with a principal place of business at Weisshausmatte 6460 Altdorf, Switzerland.

¹ All of the Gnosis entities hereafter will be referred to collectively as "Gnosis."

- 3. Plaintiff SAMSF is a not for profit research corporation organized and existing under the laws of Alabama and having a principal place of business at 307 University Boulevard, P.O. Box U-1060, Mobile Alabama.
- 4. Plaintiff Pamlab is a limited liability company organized under the laws of Louisiana, having a principal place of business in Covington, St. Tammany Parish, Louisiana.
- 5. Upon information and belief, Defendant Macoven is a corporation organized under the laws of Texas having its principal place of business at 33219 Forest West Dr., Magnolia, Texas 77354.
- 6. Upon information and belief, Gnosis S.p.A. is an Italian corporation with its principal place of business at Via Lavoratori Autobianchi 1, 20033 Desio (MI) Italy.
- 7. Upon information and belief Gnosis USA Inc. is a Pennsylvania corporation with its principal place of business at 169 N. Main Street, Doylestown, PA 18901.
- 8. Upon information and belief, Gnosis Bioresearch SA, is a Swiss association, with a principal place of business at Via Lischedi, CH-6592 San Antonino, Switzerland.

JURISDICTION AND VENUE

- 9. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this case arises under the United States Patent Act, 35 U.S.C. § 100, *et seq*.
- 10. This Court has personal jurisdiction over Defendants because Defendants transact business within the State of Texas, contract to supply goods or services in the State of Texas, have engaged in acts of patent infringement within the State of Texas, and have engaged in acts outside the State of Texas causing injury within the State. More specifically, Defendants market, promote, advertise, offer for sale, sell, and/or distribute their products to customers including manufacturers, wholesalers, retailers, chains, distributors, mail order houses, independent

pharmacies, managed care organizations and/or others throughout the United States, including in the Eastern District of Texas. The Defendants have purposefully and voluntarily placed their products into the stream of commerce with the expectation that they will be purchased by consumers in this District. As such, Defendants have established minimum contacts with the forum such that the exercise of jurisdiction over them would not offend traditional notions of fair play and substantial justice.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400.

BACKGROUND

A. The Patents-In-Suit

- 12. On December 7, 1999, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent No. 5,997,915 ("the '915 patent").
- 13. The '915 patent is entitled "Compositions for Human and Animal Consumption Containing Reduced Folates and Methods for Making and Using the Same."
 - 14. The '915 patent names Steven W. Bailey and June E. Ayling as inventors.
- 15. The '915 patent has been assigned to SAMSF. A true and correct copy of the '915 patent is attached as Exhibit A. Also attached as Exhibit A is the Reexamination Certificate that issued for the '915 patent on December 13, 2011.
- 16. Merck is an exclusive licensee to the '915 patent with the right to sue and recover for infringement of the '915 patent and any and all causes of actions and remedies, either legal and/or equitable, related thereto.
 - 17. Merck further has the right to sublicense the '915 patent.
- 18. Merck granted Pamlab an exclusive sublicense to the '915 patent in the field of medical foods, foods for special dietary use and prenatal and postnatal prescription vitamins.

- 19. On July 3, 2001, the USPTO duly and legally issued United States Patent No. 6,254,904 ("the '904 patent").
- 20. The '904 patent is entitled "Food and Vitamin Preparation Containing the Natural Isomer of Reduced Folates."
 - 21. The '904 patent names Steven W. Bailey as the inventor.
- 22. The '904 patent has been assigned to SAMSF. A true and correct copy of the '904 patent is attached as Exhibit B.
- 23. Merck is an exclusive licensee to the '904 patent with the right to sue and recover for infringement of the '904 patent and any and all causes of actions and remedies, either legal and/or equitable, related thereto.
 - 24. Merck further has the right to sublicense the '904 patent.
- 25. Merck granted Pamlab an exclusive sublicense to the '904 patent in the field of medical foods, foods for special dietary use and prenatal and postnatal prescription vitamins.
- 26. On January 6, 2004, the USPTO duly and legally issued United States Patent No. 6,673,381 ("the '381 patent").
- 27. The '381 patent is entitled "Uses for Food and Vitamin Preparations Containing the Natural Isomer of Reduced Folates."
 - 28. The '381 patent names Steven W. Bailey and June E. Ayling as inventors.
- 29. The '381 patent has been assigned to SAMSF. A true and correct copy of the '381 patent is attached as Exhibit C.
- 30. Merck is an exclusive licensee to the '381 patent with the right to sue and recover for infringement of the '381 patent and any and all causes of actions and remedies, either legal and/or equitable, related thereto.
 - 31. Merck further has the right to sublicense the '381 patent.

- 32. Merck granted Pamlab an exclusive sublicense to the '381 patent in the field of medical foods, foods for special dietary use and prenatal and postnatal prescription vitamins.
- 33. On February 6, 2007, the USPTO duly and legally issued United States Patent No. 7,172,778 ("the '778 patent").
- 34. The '778 patent is entitled "Food and Vitamin Preparations Containing the Natural Isomer of Reduced Folates."
 - 35. The '778 patent names Steven W. Bailey and June E. Ayling as inventors.
- 36. The '778 patent has been assigned to SAMSF. A true and correct copy of the '778 patent is attached as Exhibit D.
- 37. Merck is an exclusive licensee to the '778 patent with the right to sue and recover for infringement of the '778 patent and any and all causes of actions and remedies, either legal and/or equitable, related thereto.
 - 38. Merck further has the right to sublicense the '778 patent.
- 39. Merck granted Pamlab an exclusive sublicense to the '778 patent in the field of medical foods, foods for special dietary use and prenatal and postnatal prescription vitamins.
- 40. On March 9, 2010, the USPTO duly and legally issued United States Patent No. 7,674,490 ("the '490 patent").
- 41. The '490 patent is entitled "Food and Vitamin Preparations Containing the Natural Isomer of Reduced Folates."
 - 42. The '490 patent names Steven W. Bailey and June E. Ayling as inventors.
- 43. The '490 patent is assigned to SAMSF. A true and correct copy of the '490 patent is attached as Exhibit E.

- 44. Merck is an exclusive licensee to the '490 patent with the right to sue and recover for infringement of the '490 patent and any and all causes of actions and remedies, either legal and/or equitable, related thereto.
 - 45. Merck further has the right to sublicense the '490 patent.
- 46. Merck granted Pamlab an exclusive sublicense to the '490 patent in the field of medical foods, foods for special dietary use and prenatal and postnatal prescription vitamins.
- 47. On January 4, 2000, the USPTO duly and legally issued United States Patent No. 6,011,040 ("the '040 patent").
- 48. The '040 patent is entitled "Use of Tetrahydrofolates in Natural Stereoisomeric Form for the Production of a Pharmaceutical Preparation Suitable for Influencing the Homocysteine Level, Particularly for Assisting the Remethylation of Homocysteine."
- 49. The '040 patent names Hans Rudolf Muller, Martin Ulmann and Rudolf Moser as inventors.
- 50. The '040 patent has been assigned to Merck & Cie. A true and correct copy of the '040 patent is attached as Exhibit F.
- 51. Pamlab is an exclusive licensee to the '040 patent in the field of medical foods, foods for special dietary use and prenatal and postnatal prescription vitamins.

B. Plaintiffs' Products

- 52. Merck & Cie ("Merck") is the Swiss affiliate of Merck KGaA.
- 53. Merck provides active pharmaceutical and dietary ingredients to the pharmaceutical and nutritional industry for use in clinical trials and commercial product applications.
- 54. One such product is the dietary ingredient (6S)-N-[4-[[(2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridinyl)methyl]amino] benzoyl]-L-glutamic acid, calcium salt,

also known as L-5-methyltetrahydrofolic acid, calcium salt, or L-methylfolate, or (6S)-5-MTHF or L-5-MTHF, or synonyms thereof (hereinafter "L-methylfolate").

- 55. Merck markets this product in connection with its trademarks consisting in whole or in part of the term METAFOLIN®.
 - 56. Merck supplies L-methylfolate as a bulk substance.
- 57. Merck's licensees/customers then use METAFOLIN® brand L-methylfolate in various dietary supplements, medical foods, nutritional supplements, pregnancy vitamins, and food for special dietary use.
- 58. Merck also participates in the sale of finished products containing L-methylfolate through licensing arrangements with its licensees/customers.
- 59. Pursuant to its exclusive sublicense, Pamlab markets and sells Neevo DHA®, METANX®, Cerefolin NAC®, and DEPLIN® all of which use METAFOLIN® as an ingredient.
- 60. Neevo DHA®, METANX®, Cerefolin NAC® and DEPLIN® are covered by one or more claims of the '915, '904, '381, '778, '490 and/or '040 patents.

C. Defendants' Unlawful Conduct

- 61. Upon information and belief, Macoven is a generic pharmaceutical and nutraceutical company that develops, manufactures, markets and sells generic pharmaceutical products.
- 62. Upon information and belief, Gnosis S.p.A. Gnosis USA Inc. and Gnosis Bioresearch S.A. (collectively "Gnosis) are biotechnology companies that manufacture and sell a wide range of raw materials for the pharmaceutical, nutraceutical, cosmetic and veterinary industries.

63. Defendants offer to sell, and sell and distribute their products nationwide, including offering for sale and sale and distribution in Texas, in particular, including the Eastern District of Texas.

Macoven's Products

- 64. In particular, upon information and belief, Macoven and Gnosis work together to manufacture, market and sell Vitaciric-B.
- 65. Upon information and belief, Vitaciric-B claims to have the same ingredients as Pamlab's METANX®.
- 66. Upon information and belief, Vitaciric-B is substituted at the pharmacy level for Pamlab's METANX®.
- 67. Upon information and belief, Macoven and Gnosis also work together to manufacture, market and sell ALZ-NAC.
- 68. Upon information and belief, ALZ-NAC claims to have the same ingredients as Pamlab's Cerefolin NAC®.
- 69. Upon information and belief, ALZ-NAC is substituted at the pharmacy level for Pamlab's Cerefolin NAC®.
- 70. Upon information and belief, Macoven and Gnosis also work together to manufacture, market and sell L-methylfolate PNV DHA.
- 71. Upon information and belief, L-methylfolate PNV DHA claims to have the same ingredients as Pamlab's Neevo DHA®.
- 72. Upon information and belief, L-methylfolate PNV DHA is substituted at the pharmacy level for Pamlab's Neevo DHA®.
- 73. Upon information and belief, Macoven and Gnosis also work together to manufacture, market and sell L-methylfolate calcium, in a 7.5mg and 15 mg dosage.

- 74. Upon information and belief, Macoven's L-methylfolate calcium, 7.5mg product claims to have the same ingredient as Pamlab's DEPLIN®, 7.5 mg.
- 75. Upon information and belief, Macoven's L-methylfolate calcium, 7.5mg product is substituted at the pharmacy level for Pamlab's DEPLIN®, 7.5 mg.
- 76. Upon information and belief, Macoven's L-methylfolate calcium, 15mg product claims to have the same ingredient as Pamlab's DEPLIN®, 15 mg.
- 77. Upon information and belief, Macoven's L-methylfolate calcium, 15mg product is substituted at the pharmacy level for Pamlab's DEPLIN®, 15 mg.
- 78. Upon information and belief, Macoven and Gnosis are infringing the '915, '904, '381, '778, '490 and/or '040 patents by importing, practicing, manufacturing, using, selling and/or offering for sale in this judicial district and elsewhere the inventions claimed therein through the sale of the following products: Vitaciric-B, ALZ-NAC L-methylfolate PNV DHA, and L-methylfolate calcium, 7.5 mg and 15 mg (collectively, the "Infringing Products").
- 79. Upon information and belief, Macoven and Gnosis also actively induce infringement of the '915, '904, '381, '778, '490 and/or '040 patents.
- 80. Upon information and belief Macoven and Gnosis know that the Infringing Products are especially made or adapted for use in infringing '915, '904, '381, '778, '490 and/or '040 patents and are not suitable for a substantial noninfringing use. On information and belief, Macoven and Gnosis thus contribute to the infringement of the '915, '904, '381, '778, '490 and/or '040 patents.
- 81. The foregoing actions by Macoven and Gnosis constitute infringement of the '915, '904, '381, '778, '490 and/or '040 patents.
- 82. On information and belief, Macoven and Gnosis acted without a reasonable basis for believing that they would not be liable for infringing the '915, '904, '381, '778, '490 and/or

'040 patents, actively inducing infringement of the '915, '904, '381, '778, '490 and/or '040 patents, and/or contributing to the infringement by others of the '915, '904, '381, '778, '490 and/or '040 patents.

Gnosis' Products

- 83. Upon information and belief, Gnosis is a manufacturer of L-methylfolate ingredients.
- 84. Upon information and belief, Gnosis sells its L-methylfolate ingredients to customers in the United States.
- 85. Upon information and belief, Gnosis's customers include, among others, Macoven.
- 86. Upon information and belief, Gnosis's customers incorporate its L-methylfolate ingredients in to finished products.
- 87. Upon information and belief, some of the finished products that incorporate Gnosis's L-methylfolate product include additional vitamins and/or nutrients.
- 88. Upon information and belief, Gnosis has knowledge of its customers' products that incorporate its L-methylfolate ingredients as Gnosis's name and trademark appear on its customers' product labels.
- 89. Upon information and belief, Gnosis had knowledge of the '915, '904, '381, '778, '490 and/or '040 patents.
- 90. Upon information and belief, Gnosis knows, for example, that Macoven's Vitaciric-B, ALZ-NAC, L-methylfolate PNV DHA and L-methylfolate products, through incorporation of Gnosis's L-methylfolate ingredients, infringe the '915, '904, '381, '778, '490 and/or '040 patents.

- 91. Upon information and belief, Gnosis knows, that other of its customers' products, through incorporation of Gnosis's L-methylfolate ingredients, infringe the '915, '904, '381, '778, '490 and/or '040 patents.
- 92. Upon information and belief, Gnosis is actively inducing the infringement of the '915, '904, '381, '778, '490 and/or '040 patents.
- 93. Upon information and belief, Gnosis acted without a reasonable basis for believing that it would not be liable for actively inducing infringement of the '915, '904, '381, '778, '490 and/or '040 patents.
- 94. The foregoing actions by Gnosis constitute active inducement of infringement of the '915, '904, '381, '778, '490 and/or '040 patents.
- 95. Upon information and belief Gnosis know that its L-methylfolate ingredients are especially made or adapted for use in infringing '915, '904, '381, '778, '490 and/or '040 patents and are not suitable for a substantial noninfringing use. On information and belief, Gnosis thus contributes to the infringement of the '915, '904, '381, '778, '490 and/or '040 patents.
- 96. The foregoing actions by Gnosis constitute infringement of the '915, '904, '381, '778, '490 and/or '040 patents.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 5,997,915

- 97. Plaintiffs incorporate herein and reallege, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 96 above, inclusive.
- 98. Upon information and belief, Defendants have infringed and continue to infringe, directly and/or indirectly, the claims of the '915 patent, either literally or under the doctrine of equivalents, by importing, practicing, manufacturing, using, selling and/or offering for sale in the United States products falling within the scope of one or more claims of the '915 patent.

- 99. Plaintiffs have been damaged by Defendants' past and continuing infringement of the '915 patent in an amount to be determined at trial.
- 100. Plaintiffs have been and continue to be irreparably injured by Defendants' past and continuing infringement of the '915 patent, and Defendants' infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.
- 101. Plaintiffs have suffered and are suffering monetary damages from Defendants' unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.
- 102. Upon information and belief, Defendants have knowledge of the '915 patent by virtue of the identification of the '915 patent on the METANX®, Neevo DHA® and Cerefolin NAC® product labels, package information and marketing materials. Accordingly, Defendants' infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '915 patent, and Plaintiffs accordingly are entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as their attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 6,254,904

- 103. Plaintiffs incorporate herein and reallege, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 102 above, inclusive.
- 104. Upon information and belief, Defendants have infringed and continue to infringe, directly and/or indirectly, the claims of the '904 patent, either literally or under the doctrine of equivalents, by importing, practicing, manufacturing, using, selling and/or offering for sale in the United States products falling within the scope of one or more claims of the '904 patent.

- 105. Plaintiffs have been damaged by Defendants' past and continuing infringement of the '904 patent in an amount to be determined at trial.
- 106. Plaintiffs have been and continue to be irreparably injured by Defendants' past and continuing infringement of the '904 patent, and Defendants' infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.
- 107. Plaintiffs have suffered and are suffering monetary damages from Defendants' unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.
- 108. Upon information and belief, Defendants have knowledge of the '904 patent by virtue of the identification of the '904 patent on the METANX®, Neevo DHA® and Cerefolin NAC® product labels, package information and marketing materials. Accordingly, Defendants' infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '904 patent, and Plaintiffs accordingly are entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as their attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 6,673,381

- 109. Plaintiffs incorporate herein and reallege, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 108 above, inclusive.
- 110. Upon information and belief, Defendants have indirectly infringed and continue to indirectly infringe the claims of the '381 patent, either literally or under the doctrine of equivalents, by importing, practicing, manufacturing, using, selling and/or offering for sale in the United States products falling within the scope of one or more claims of the '381 patent.

- 111. Plaintiffs have been damaged by Defendants' past and continuing infringement of the '381 patent in an amount to be determined at trial.
- 112. Plaintiffs have been and continue to be irreparably injured by Defendants' past and continuing infringement of the '381 patent, and Defendants' infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.
- 113. Plaintiffs have suffered and are suffering monetary damages from Defendants' unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.
- 114. Upon information and belief, Defendants have knowledge of the '381 patent by virtue of Defendants' knowledge of related patents Pamlab's product labels, package information and marketing materials. Accordingly, Defendants' infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '381 patent, and Plaintiffs accordingly are entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as their attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

COUNT IV

INFRINGEMENT OF U.S. PATENT NO. 7,172,778

- 115. Plaintiffs incorporate herein and reallege, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 114 above, inclusive.
- 116. Upon information and belief, Defendants have infringed and continue to infringe, directly and/or indirectly, the claims of the '778 patent, either literally or under the doctrine of equivalents, by importing, practicing, manufacturing, using, selling and/or offering for sale in the United States products falling within the scope of one or more claims of the '778 patent.
- 117. Plaintiffs have been damaged by Defendants past and continuing infringement of the '778 patent in an amount to be determined at trial.

- 118. Plaintiffs have been and continue to be irreparably injured by Defendants' past and continuing infringement of the '778 patent, and Defendants infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.
- 119. Plaintiffs have suffered and are suffering monetary damages from Defendants' unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.
- 120. Upon information and belief, Defendants have knowledge of the '778 patent by virtue of Defendants' knowledge of related patents on Pamlab's product labels, package information and marketing materials. Accordingly, Defendants' infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '778 patent, and Plaintiffs accordingly are entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as their attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

COUNT V

INFRINGEMENT OF U.S. PATENT NO. 7,674,490

- 121. Plaintiffs incorporate herein and reallege, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 120 above, inclusive.
- 122. Upon information and belief, Defendants have infringed and continue to infringe, directly and/or indirectly, the claims of the '490 patent, either literally or under the doctrine of equivalents, by importing, practicing, manufacturing, using, selling and/or offering for sale in the United States products falling within the scope of one or more claims of the '490 patent.
- 123. Plaintiffs have been damaged by Defendants past and continuing infringement of the '490 patent in an amount to be determined at trial.

- 124. Plaintiffs have been and continue to be irreparably injured by Defendants' past and continuing infringement of the '490 patent, and Defendants infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.
- 125. Plaintiffs have suffered and are suffering monetary damages from Defendants' unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.
- 126. Upon information and belief, Defendants have knowledge of the '490 patent by virtue of Defendants' knowledge of related patents on Pamlab's product labels, package information and marketing materials. Accordingly, Defendants' infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '490 patent, and Plaintiffs accordingly are entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as their attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

COUNT VI

INFRINGEMENT OF U.S. PATENT NO. 6,011,040

- 127. Plaintiffs incorporate herein and reallege, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 126 above, inclusive.
- 128. Upon information and belief, Defendants have infringed and continue to infringe, directly and/or indirectly, the claims of the '040 patent, either literally or under the doctrine of equivalents, by importing, practicing, manufacturing, using, selling and/or offering for sale in the United States products falling within the scope of one or more claims of the '040 patent.
- 129. Plaintiffs have been damaged by Defendants' past and continuing infringement of the '040 patent in an amount to be determined at trial.

- 130. Plaintiffs have been and continue to be irreparably injured by Defendants' past and continuing infringement of the '040 patent, and Defendants' infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.
- 131. Plaintiffs have suffered and are suffering monetary damages from Defendants' unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.
- 132. Upon information and belief, Defendants have knowledge of the '040 patent by virtue of the identification of the '040 patent on the METANX®, Neevo DHA®, Cerefolin NAC® and DEPLIN® product labels, package information and marketing materials. Accordingly, Defendants' infringement has been and continues to be deliberate, willful, intentional, and with knowledge of the existence of the '040 patent, and Plaintiffs accordingly are entitled to recover enhanced damages pursuant to 35 U.S.C. § 284, as well as their attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

- A. Enter judgment that Defendants have directly and/or indirectly infringed the claims of the '915 patent and that Defendants' infringement has been willful;
- B. Enter judgment that Defendants have directly and/or indirectly infringed the claims of the '904 patent and that Defendants' infringement has been willful;
- C. Enter judgment that Defendants have directly and/or indirectly infringed the claims of the '381 patent and that Defendants' infringement has been willful;
- D. Enter judgment that Defendants have directly and/or indirectly infringed the claims of the '778 patent and that Defendants' infringement has been willful;

E. Enter judgment that Defendants have directly and/or indirectly infringed the

claims of the '490 patent and that Defendants' infringement has been willful;

F. Enter judgment that Defendants have directly and/or indirectly infringed the

claims of the '040 patent and that Defendants' infringement has been willful;

G. Permanently enjoin Defendants, and all those in active concert or participation

with it, from directly and/or indirectly infringing the '915, '904, '381, '778 '490 and '040

patents, pursuant to 35 U.S.C. § 283;

H. Award Plaintiffs damages in an amount to be proved at trial that will adequately

compensate Plaintiffs for Defendants' infringement, but under no circumstances an amount less

than a reasonable royalty, as authorized by 35 U.S.C. § 284;

I. Increase the damages sustained by Plaintiffs up to three times the amount of their

actual damages, as authorized by 35 U.S.C. § 284;

J. Award Plaintiffs their attorneys' fees and other expenses of litigation pursuant to

35 U.S.C. § 285;

K. Award Plaintiffs prejudgment interest and costs pursuant to 35 U.S.C. § 284; and

L. The Court grant such other, different, and additional relief as the Court deems just

and proper.

Dated: January 19, 2012

Respectfully submitted,

/s/ Dwayne C. Norton

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